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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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09/811,546

03/20/2001

Karl Kolter

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04/23/2009

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

04/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/811,546 | Applicant(s) KOLTER ET AL. | |
| | Examiner ERIC E. SILVERMAN | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14,16-18 and 22-33 is/are pending in the application.
- 4a) Of the above claim(s) 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-14,16-18,22-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3-14, 16-18, 22-33 are pending, claims 25 and 26 are withdrawn, and claims 1, 3-14, 16-18, 22-24 and 27-33 are treated on the merits in this action.

Response to Amendment

The affidavit under 37 CFR 1.132 filed 3/9/2009 is sufficient to overcome the rejection of claim 30 based upon indefiniteness under 35 U.S.C. 112, second paragraph.

The affidavit under 37 CFR 1.132 filed 3/9/2009 is insufficient to overcome the rejection of claims 1, 4, 7-12, 14, 16-18, 22, 24, and 31-33 as anticipated by Ortega, is insufficient to overcome the rejection of claims 1, 3-14, 16-18, 22-24, and 27-33 as obvious over Kolter in view of Ortega, and is insufficient to overcome the rejection of claims 1, 3-14, 16-18, 22-24 and 27-33 as obvious over Kolter in view of Ortega and Matthews as set forth in the last Office action because: 1) The declaration avers that the "formulated mixture" or "pre-formulated mixture" of the claims has a particular meaning which is not met by the art. The BPAI has determined the meaning of these terms in this application. *Ex parte Kolter* Appeal 2008-3377 (BPAI 20089) at 4. A formulated mixture of "polyvinyl acetate and polyvinylpyrrolidone is ... an intimate mixture of a lipophilic with a hydrophilic polymer." *Id.* (citing instant specification). While "pre-formulated mixture," is not specifically defined, it is understood to mean mixture manufactured as a formulated mixture and later subject to some other processing step. The declaration attempts to supply a new meaning of this term. In accordance with the abovementioned decision of the BPAI and the principle of *res*

Art Unit: 1618

judicata, issues decided in the appeal are not subject to further review by the Examiner.

See MPEP 706.03(w). The BPAI determined that the claims require a formulated mixture, determined the meaning of this term, and, by affirming the examiner's rejections, necessarily found that the art reads on this term. The principle of *res judicata* requires the Examiner to follow the BPAI decision in this issue.

(2) The declaration alleges that the tablet press settings in Ortega would not lead to the hardnesses of claim 33. This statement is a conclusion, unsupported by any evidence or technical reasoning. The declarant did not test the tablets of Ortega, but merely conjectured as to what their hardness would be. On the contrary, the artisan recognizes that the settings on a tablet press do not correspond to the hardness of the final tablet, but other factors, such as the nature of the drug and excipients, are also important. Further, it is noted that instant specification discloses that 10 kN (kg) is an appropriate tablet press setting to achieve inventive tablets, as per instant Example 3. 10 kg is within the range of pressures used by Ortega. Because the ingredients of the art and the compression force in the art are the same as those in the claims, it is reasonable to conclude that the tablet hardness will also be the same in the art as in the claims.

(c) The declarant makes various legal conclusions as to what he would have been motivated to do, and as to what the prior art (specifically Matthews) would teach the artisan. The weight given to a declaration relates to the amount of factual evidence in the declaration. *In re Buchner*, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991). The

Art Unit: 1618

declaration at hand has no factual evidence, but merely states the declarants opinions.

It is therefore entitled to little weight.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7-12, 14, 16-18, 22, 24, and 31-33 remain rejected under 35

U.S.C. 102(b) as being anticipated by Ortega.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-14, 16-18, 22-24, and 27-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kolter in view of Ortega.

Claims 1, 3-14, 16-18, 22-24, and 27-33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kolter in view of Ortega and Matthews.

Response to Arguments

Applicants' arguments were fully considered but are not persuasive.

Most of Applicants arguments relate to issues that were already decided by the BPAI, such as the meaning of "formulated mixture." The BPAI's holdings on these issues is not reviewable by the Examiner. Applicants' arguments regarding claim 33

Art Unit: 1618

were addressed above. Applicants' arguments about Matthews teaching of coating are not germane, because the claims no longer require a coating.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618